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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/631,981

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George Martinez

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

03/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/631,981	Applicant(s) MARTINEZ, GEORGE	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 7-9, 13, 14, 17, 18, 20, 21-23 and 25 of copending Application No. 11/089207. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations that are missing from the co-pending application are features that inherent or well known in the art. The copending application claims an inner element; a non-metallic intermediate element that is a hydrogel; and an outer element defining a helically wound open coil that has an open area through which the intermediate element is exposed. The pending application does not claim that the hydrogel swells through the gaps of the outer coil to form an undulating configuration

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defining a chain of convexly curved arcuate segments. It is old and well known for hydrogels to expand to 600 times their original size. It therefore would be inherent that the hydrogel would expand through the openings of the coil, with the coil limiting some of the expansion thus resulting in the undulating configuration. Regarding the limitation that the inner and outer elements are in intimate contact along the length or that the inner element and the outer element are attached at the proximal and distal ends, attaching an outer and inner coaxial elements is old and well known in the art to ensure ease of delivery and therefore the modification would have been obvious. Regarding the coupling element, it is old and well known to use a coupling element to fixedly couple an outer element to an inner element. Regarding the biocompatible material including a therapeutic or bioactive agent, it is old and well known to incorporate drug delivery with implants.

3. This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 1, 2, 4, 10-12, 14-17, 19, 25-27, 40, 41, 43, 49, 50, 52-55, 57, 63, 64, rejected under 35 U.S.C. 102(e) as being anticipated by Sepetka (US 2002/0169473).

6. Sepetka discloses a vaso-occlusive device implant, comprising:
an elongate, flexible, filamentous inner element (352); a non-metallic intermediate element coaxially surrounding the inner element and in intimate contact therewith substantially along the length of the inner member (Para [0164] where the intermediate element is drug coating); and an outer element coaxially surrounding the intermediate element and in intimate contact therewith (354), the outer element defining a gap or opening through which the intermediate element is exposed and through which the intermediate element is capable of swelling (see for example Figs 62-64, 67, 68). The inner element comprises a microcoil (in the sense that micro is extremely small and therefore not being given patentable weight). The outer element includes an open-wound, helically-coiled portion that defines the gap or opening through which the intermediate element is exposed. The proximal and distal end sections of the outer element are respectively attached to the distal and proximal ends of the inner element (although not necessarily fixedly attached, the coils are attached in the sense that are joined together as one element). Each of the proximal and distal end sections of the outer element includes a close-wound helical coil section (for example Fig. 67, 68).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3, 5-9, 13, 18, 28, 20-24, 28-39, 42, 44-48, 51, 56, 58-62 rejected under 35 U.S.C. 103(a) as being unpatentable over Sepetka (US 2002/0169473) in view of Rosenthal (US 7,006,904).

9. Sepetka discloses the limitations substantially as claimed as stated above except for the intermediate element being an expansile polymeric material that is a hydrogel. Sepetka does disclose that an intermediate element that is for providing drug delivery.

10. Rosenthal teaches an expansile polymeric material element that is for providing drug delivery and consists essentially of hydrogel (C3:L37-39; C4:L6, 11) that expands in response to change in temperature or pH (C 3: L33-41; C4:L10-14).

11. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of a hydrogel for drug delivery. One of ordinary skill would have been capable of applying this known technique of enhancement to a base device (occlusive device) in order to yield predictable results. If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, applying the technique to a similar device would have been obvious.

12. The modified device would meet the limitation that the intermediate element, when expanded, extends through the openings of the outer element to form an exterior surface having an undulating configuration defining a chain of convexly-curved arcuate segments. Sepetka discloses the use of one coil as the outer element (Para [0164] *one or more secondary coils*) It is well known in the art that hydrogels can expand up to 600 times their original size. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01).

13. Sepetka in view of Rosenthal does not disclose a coupling element attached to the proximal end of the inner element and to the proximal end of the outer element.

14. It would have been well within the skill of the ordinary artisan to incorporate a coupling element at the proximal ends of the coils since it is old and well known to use coupling elements (i.e. welds, radiopaque markers, sutures) in medical implants having coaxially surrounding elements (i.e. embolic coils, stent-grafts, embolic filters).

Response to Arguments

15. Applicant's arguments with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731